K000628

MAR 1 3 2000

510(k) SUMMARY

The Summary of Safety and Effectiveness on the Wallace Oocyte Retrieval Set reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Applicant	David Poore Quality Assurance Manager SIMS Portex Ltd Hythe Kent CT21 6JL UK
Telephone	44 1303 260551
Facsimile	44 1303 266761
Date	January 10, 2000
Name	Wallace Oocyte Retrieval Set
Classification	Assisted Reproduction Needles, 21 CFR 884.6100
Predicate	884.6100 Assisted reproduction needles 21 CFR Part 884 [Docket No. 97N – 0335] Obstetrics and Gynecologic Devices: Reclassification of Medical Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures. Effective Date: October 13, 1998
Description	Wallace Oocyte Retrieval Set is a single-use device provided sterile for ultrasound-guided, transvaginal recovery and collection of oocytes from ovarian follicles. The set consists of a single-lumen, stainless steel needle attached to polyurethane (Tecoflex) tubing 950mm long, using a 25mm long medical grade silicone sleeve. The needle is 33cm in length and available in 16 gauge or 17 gauge, each having echomarking at the distal tip for ultrasound reflection and a plastic hub at the proximal end for ease of guidance by hand. Tubing is attached to the hub of the needle and protrudes a total distance of 1400mm until it terminates in a Luer lock. The tubing is split after 950mm by a silicone bung.
Intended Use	The Wallace Oocyte Retrieval Set is intended for ultasound-guided, transvaginal recovery and collection of oocytes from ovarian follicles.
Contraindications	Not intended for use in the presence of or after recent pelvic inflammatory disease or chronic cervical infection. Not intended for placement of fertilized oocyte(s) into the fallopian tube.
Caution	Federal law (U.S.A.) restricts this device to sale by or on the order of a physician
Technological Characteristics	There are no published standards for these particular types of products, and as such tests have been developed which are considered sufficient to ensure the efficacy and safety of the device(s) for its intended use. Such tests include – Visual; Dimensional; Functional; one-cell Mouse Embryo Assay; and Bacterial Endotoxin (Limulus Amoebocyte Proygen) Test.
Data Submitted	The biological safety assessment of the Wallace Oocyte Retrieval Set has been performed in accordance with the International Standard ISO 10993, Part 1:1994, "Biological Evaluation of medical Devices: Evaluation and Testing." In addition to ISO 10993 the selection of tests, taking into consideration the particular application of the product e.g. collection of human oocytes, embryo toxicity and bacterial endotoxin tests were performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2000

Mr. Giles Bishop
Research and Development Dept.
SIMS Portex Limited
Hythe
Kent CT21 6JL
UNITED KINGDOM

Re: K000628
Wallace Oocyte Retrieval Set
Dated: February 22, 2000
Received: February 24, 2000
Regulatory Class: II
21 CFR §884.6100/Procode: 85 MQE

Dear Mr. Bishop:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

ITEM		PRESENT YES	PRESENT NO	NEEDED (Y/N/?)
9.	510(k) summary or statement	X		
10.	If Class III, Class III Certificate & Summary		X	
11.	If kit, kit certification		X	

510(k) Number (if known): K000628

Device Name: Wallace Oocyte Retrieval Set – 16G, Wallace Oocyte Retrieval Set – 17G

Indications For Use:

The Wallace Oocyte Retrieval Sets are intended for ultrasound-guided transvaginal collection of oocytes from ovarian follicles for use in assisted conception procedures, e.g. *in vitro* fertilization.

CONTRAINDICATION:

Not intended for use in the presence of or after recent pelvic inflammatory disease or chronic cervical infection.

Not intended for placement of fertilized oocyte(s) into the fallopian tube.

CAUTION:

Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 01.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000628